

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

1. (original) A mask assembly for positive pressure ventilation, comprising:
 - a mask body assembly constructed and arranged to sealingly engage at least a portion of a patient's face so as to provide the patient with pressurized breathable gas;
 - a mask frame connected to the mask cushion, the mask frame having one or more receiving structures for receiving engaging portions of strap attachment mechanisms; and
 - a headgear assembly comprising
 - one or more straps, each of the one or more straps having a strap attachment mechanism constructed and arranged to engage the receiving structures of the mask frame; and
 - an active tensioning element coupled to the one or more straps to automatically adjust tension in the one or more straps in accordance with the pressure of the breathable gas supplied to the patient.
2. (original) The mask assembly of claim 1, wherein the one or more straps are substantially inextensible.

3. (currently amended) The mask assembly of ~~any one of claims 1 and 2~~
claim 1, wherein the active tensioning element is an inflatable bladder, such as an
occipital pneumatic pillow or a raviolus, coupled to the one or more straps.

4. (original) The mask assembly of claim 3, wherein the inflatable bladder is
inflated by a portion of the pressurized breathable gas that is supplied to the mask
assembly.

5. (currently amended) The mask assembly of ~~any one of claims 3 and 4~~
claim 3, wherein pressure in the inflatable bladder increases when the pressure of the
breathable gas supplied to the patient increases.

6. (currently amended) The mask assembly of ~~any one of claims 3-5~~ claim 3,
further comprising a conduit having two ends, a first end adapted to engage a
breathable gas conduit and a second end adapted to engage the inflatable bladder so
as to be in fluid communication therewith.

7. (original) A method of controlling strap tension in a non-invasive positive
pressure ventilation mask: coupling an active tensioning element to the straps of the
mask; and causing the active tensioning element to automatically increase the tension
in the straps when the pressure of the breathable gas supplied to the patient increases.

8. (original) The method of claim 7, wherein the active tensioning element is an inflatable bladder such as an occipital pneumatic pillow or a raviolus.

9. (original) The method of claim 8, wherein causing the active tensioning element to automatically increase the tension in the straps comprises automatically inflating the inflatable bladder when the pressure of the breathable gas supplied to the patient increases.

10. (original) A substantially inextensible headgear assembly constructed and arranged to be connected to a positive pressure ventilation mask, the headgear comprising:

one or more substantially inextensible straps; and
an inflatable bladder, such as an occipital pneumatic pillow or a raviolus,
in force-transmitting relation with the one or more straps.

11. (original) A mask assembly for non-invasive positive pressure ventilation, comprising:

a mask frame having substantially rigid side portions connected by flexible base and apex portions;

a mask body assembly coupled to the mask frame and moveable with respect thereto; and

headgear constructed and arranged to be releasably connected to the mask frame, the headgear including an active tensioning element in force-transmitting relation therewith, the active tensioning element being constructed and adapted to automatically adjust headgear tension while the mask assembly is in use.

12. (original) The mask assembly of claim 11, wherein the active tensioning element is an inflatable bladder such as an occipital pneumatic pillow or a raviolus.

13. (original) A mask assembly for non-invasive positive pressure ventilation adapted to be positioned on a face of a patient, comprising:

a mask frame having substantially rigid side portions connected by flexible base and apex portions, the apex and base portions defining a longitudinal axis;

a mask body assembly coupled to the mask frame;

a mask cushion coupled to the mask body;

and headgear comprising at least one strap constructed and arranged to be operatively positioned along the side of a patient's head;

wherein the mask frame can be resiliently flexed around the face of the patient about the longitudinal axis to accommodate the shape of the patient's face and secured to the at least one strap.

14. (original) A method for holding a mask sealingly against a patient's face, comprising:

placing an occipital pneumatic pillow against a portion of the head and/or neck;

passing straps over the pillow, the straps passing forward to attach to the mask; and

inflating the pillow with a pressure P_{bladder} which is an affine function of mask pressure P_{mask} :

$$P_{\text{bladder}} = P_0 + A_{\text{mask}} P_{\text{mask}}$$

where P_0 is a positive pressure sufficient to cause the mask to seal at the lowest intended usage pressure, and A_{mask} is the lesser of the area of contact between the pillow and the straps posteriorly, and the area of contact between the pillow and the back of the head anteriorly.

15. (original) The method of claim 14, wherein the inflating the pillow with a pressure which is an affine function of mask pressure comprises:

measuring mask pressure with a pressure transducer, to produce a signal proportional to mask pressure;

applying the signal to an amplifier with adjustable gain and offset;

applying the output of the amplifier to a voltage controllable pressure source;

inflating said pillow with gas from said pressure source;

adjusting said offset so that the mask seals at the lowest required pressure; and

adjusting said gain so that the mask seals at the highest required pressure.

16. (original) The method of any one of claims 14 and 15, wherein, if the signal V_{pt} from the pressure transducer is $V_{pt} = K_{pt} P_{mask}$, the controllable pressure source produces a pressure $P_C = K_C V_C$, the projection in the posterior direction of the contact area of the mask with the face is A_{mask} , the projection in the anterior direction of the area of contact of the straps with the posterior surface of the pillow is $A_{bladder}$, and the force required to produce a seal at zero pressure is F_0 , then the amplifier produces an output voltage: $V_{out} = F_0/A_{bladder} + A_{mask}/A_{bladder} K_C/K_{pt} V_{in}$.

17. (currently amended) The method of ~~any one of claims 14-16~~ claim 14, wherein inflating the pillow with a pressure which is an affine function of mask pressure comprises:

connecting the mask via a first hose to a first cylinder containing a first piston, said first piston in turn connected via a linkage to a second piston in a second cylinder, said second cylinder connected via a second hose to said pillow; and biasing said linkage so as to inflate said pillow sufficiently to cause the mask to seal at the lowest intended usage pressure.

18. (original) An apparatus for holding a mask sealingly against a patient's face, comprising:

a first set of extensible straps, passing from the back of the head forwards to the mask, said straps being tightened sufficiently to hold said mask sealingly against the face at the lowest intended usage pressure;

a second set of inextensible straps, again passing from the back of the head forwards to the mask, and lying over the first set ; and

an inflatable occipital pneumatic pillow placed at the back of the head, between the first and second set of straps, said pillow being in pneumatic communication with the air in the mask.

19. (original) A mask assembly for application of Non-Invasive Positive Pressure Ventilation to a patient, comprising:

a frame including a main body including at least one aperture configured to receive a supply of breathable gas under pressure, said frame including at least one selected portion provided to the main body, said selected frame portion being adjustable relative to the main body; and

a cushion provided to the frame, the cushion being structured to provide an interface with the patient, said cushion, upon application of positive pressure, applying a force to the patient, said force being adjustable in accordance with 1) the position of the selected frame portion relative to the main body for a given value of said positive pressure; and/or 2) variations in the positive pressure.

20. (original) The mask assembly of claim 19, further comprising at least one headgear connector portion provided to the frame portion, said frame portion being movable in accordance with change in headgear strap tension to thereby adjust the force applied to the sides of the patient's nose and/or face in use.

21. (original) The mask assembly of claim 19, wherein the frame includes an adjustment mechanism including at least one and preferably a plurality of spaced knobs operable to change the relative positioning between the main body and the frame portion.

22. (original) The mask assembly of claim 19, wherein the selected frame portion includes a flexible member supporting the cushion.

23. (original) The mask assembly of claim 19, wherein the main body and the selected frame portion are provided two separate parts that are coupled to one another.

24. (original) The mask assembly of claim 19, wherein the main body and the selected portion are moveable by a camming mechanism.

25. (original) The mask assembly of claim 19, wherein the cushion includes at least one inflatable element therein, to adjust an effective stiffness and/or an effective fit with the patient.

26. (original) The mask assembly of claim 25, wherein the inflatable element is provided to selectively adjust a size of the nasal bridge region of the cushion.

27. (original) The mask assembly of claim 19, wherein the selected frame portion includes each lateral side of the frame which is made of a flexible material.

28. (original) The mask assembly of claim 19, wherein the cushion includes at least one element providing for multiple stiffening rates of the cushion upon changes in the force.

3029. (currently amended) A cushion assembly for a mask used for treatment of sleep disordered breathing, the cushion assembly comprising:

a cushion flange of relatively rigid material, the cushion flange including a front side adapted for connection to a body of the mask and a rear side opposite the front side;

an undercushion connected to the cushion flange and extending toward the rear side, the undercushion having a first stiffness;

a membrane connected to the cushion flange and extending toward the rear side, the membrane having a shape generally matching a shape of the undercushion and surrounding the undercushion, the membrane having a second stiffness smaller than the first stiffness, the membrane being adapted to engage a

wearer's face and form a seal between the mask and the wearer's face upon engagement ; and

a flexible element disposed between the undercushion and the membrane, the flexible element having at least a third stiffness larger than the second stiffness and smaller than the first stiffness.

3130. (currently amended) A cushion assembly according to claim 30, wherein the flexible element is formed of multiple segments.

3231. (currently amended) A cushion assembly of ~~any one of claims 30 and 31~~ claim 30, wherein the flexible element is formed of foam, and the flexible element is formed of silicone.

3332. (currently amended) A cushion assembly for a mask used for treatment of sleep disordered breathing, the cushion assembly comprising: a cushion flange of relatively rigid material, the cushion flange including a front side adapted for connection to a body of the mask and a rear side opposite the front side; a membrane connected to the cushion flange and extending toward the rear side, the membrane having a first stiffness, the membrane being adapted to engage a wearer's face and form a seal between the mask and the wearer's face upon engagement; a flexible element disposed between the membrane and the cushion flange, the flexible element having at least a second stiffness larger than the first stiffness; and a retainer engaging the flexible

element in support thereof, the flexible element being disposed between the cushion flange and the retainer.

3433. (currently amended) A cushion assembly for a mask used for treatment of sleep disordered breathing, the cushion assembly comprising: a first layer, the first layer including a front side adapted for connection to a body of the mask and a rear side opposite the front side; and a second layer connected to the first layer and extending from the front side of the first layer toward the rear side, the second layer defining a cushion shape and being adapted to engage a wearer's face and form a seal between the mask and the wearer's face upon engagement and compress upon application of a force to the cushion assembly.